

# CDER GUIDANCES

## NEW/REVISED/WITHDRAWN

01/01/2002 – 9/19/2002

(sorted by date)

Title	Subject	Level at Date of Issue	Publication/ Withdrawal Date	Status
Available Therapy	Clinical Medical Draft	Level 1	02/07/2002	New
Draft Recommendations for the Revision of the Permitted Daily Exposures for Two Solvents, N-Methylpyrrolidone and Tetrahydrofuran, According to the Maintenance Procedures for the Guidance Q3C Impurities: Residual Solvents	ICH Draft – Quality	Level 1	02/12/2002	New
Exercise-Induced Bronchospasm (EIB) – Development of Drugs to Prevent EIB	Clinical Medical Draft	Level 1	02/20/2002	New
Inhalational Anthrax (Post Exposure) -- Developing Antimicrobial Drugs	Clinical Antimicrobial Draft	Level 1	03/18/2002	New
Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions	Procedural	Level 1	03/18/2002	New
PET Drug Products - Current Good Manufacturing Practice	Compliance Draft	Level 1	04/01/2002	New
Exposure-Response Relationships: Study Design, Data Analysis; and Regulatory Applications	Clinical Pharmacology Draft	Level 1	04/02/2002	New
E2BM - Data Elements for Transmission of Individual Case Safety Reports	ICH – Efficacy	Level 1	04/03/2002	Revised
IND Exemptions for Studies of Lawfully Marketed Cancer Drug or Biological Products	Clinical Medical Draft	Level 1	04/09/2002	New
Special Protocol Assessment	Procedural	Level 1	05/17/2002	New
Blend Uniformity Analysis	Generic Drug Draft	Level 1	05/17/2002	Withdrawn
Topical Dermatological Drug Product NDAs and ANDAs – In Vivo Bioavailability, Bioequivalence, In Vitro Release and Associated Studies	Biopharmaceutics Draft	Level 1	05/17/2002	Withdrawn
Carcinogenicity Study Protocol Submissions	Pharmacology/Toxicology	Level 1	05/23/2002	New
Q1E – Evaluation of Stability Data	ICH Draft – Quality	Level 1	06/14/2002	New
M2 – Electronic Common Technical Document Specification	ICH Draft – Joint Safety/Efficacy (Multidisciplinary)	Level 1	06/14/2002	New
Q1F – Stability Data Package for Registration in Climatic Zones III and IV	ICH Draft – Quality	Level 1	06/14/2002	New
S7B – Safety Pharmacology Studies for Assessing the Potential for Delayed Ventricular Repolarization (QT Interval Prolongation) by Human Pharmaceuticals	ICH Draft – Safety	Level 1	06/14/2002	New
Providing Electronic Submissions in Electronic Format – ANDAs	Electronic Submissions	Level 1	06/27/2002	New
Prescription Drug Marketing Act Regulations for Donation of Prescription Drug Samples to Free Clinics	Compliance Draft	Level 1	06/27/2002	New
Nasal Spray and Inhalation Solution, Suspension, and Spray Drug Products -- Chemistry, Manufacturing, and Controls Documentation	Chemistry	Level 1	07/05/2002	New

Acetaminophen, Aspirin and Codeine Phosphate Tablets and Acetaminophen, Aspirin and Codeine Phosphate Capsules	Labeling	Level 1	07/05/2002	Withdrawn
Acetaminophen and Codeine Phosphate Oral Solution and Oral Suspension	Labeling	Level 1	07/05/2002	Withdrawn
Alprazolam Tablets	Labeling	Level 1	07/05/2002	Withdrawn
Amiloride Hydrochloride and Hydrochlorothiazide Tablets USP	Labeling	Level 1	07/05/2002	Withdrawn
Amlodipine Besylate Tablets	Labeling	Level 1	07/05/2002	Withdrawn
Astemizole Tablets	Labeling	Level 1	07/05/2002	Withdrawn
Atenolol Tablets	Labeling	Level 1	07/05/2002	Withdrawn
Butalbital, Acetaminophen and Caffeine Tablets USP or Butalbital, Acetaminophen and Caffeine Capsules USP	Labeling	Level 1	07/05/2002	Withdrawn
Butalbital, Acetaminophen, Caffeine and Hydrocodone Bitartrate Tablets	Labeling	Level 1	07/05/2002	Withdrawn
Butorphanol Tartrate Injection USP	Labeling	Level 1	07/05/2002	Withdrawn
Captopril and Hydrochlorothiazide Tablets USP	Labeling	Level 1	07/05/2002	Withdrawn
Captopril Tablets	Labeling	Level 1	07/05/2002	Withdrawn
Carbidopa and Levodopa Tablets USP	Labeling	Level 1	07/05/2002	Withdrawn
Cimetidine Hydrochloride Injection	Labeling	Level 1	07/05/2002	Withdrawn
Cimetidine Tablets USP	Labeling	Level 1	07/05/2002	Withdrawn
Cisapride Oral Suspension	Labeling	Level 1	07/05/2002	Withdrawn
Cisapride Tablets	Labeling	Level 1	07/05/2002	Withdrawn
Clindamycin Phosphate Injection, USP	Labeling	Level 1	07/05/2002	Withdrawn
Diclofenac Sodium Delayed-Release Tablets	Labeling	Level 1	07/05/2002	Withdrawn
Diltiazem Hydrochloride Extended-Release Capsules	Labeling	Level 1	07/05/2002	Withdrawn
Diphenoxylate Hydrochloride and Atropine Sulfate Oral Solution USP	Labeling	Level 1	07/05/2002	Withdrawn
Diphenoxylate Hydrochloride and Atropine Sulfate Tablets USP	Labeling	Level 1	07/05/2002	Withdrawn
Fludeoxyglucose F18 Injection	Labeling	Level 1	07/05/2002	Withdrawn
Flurbiprofen Tablets USP	Labeling	Level 1	07/05/2002	Withdrawn
Fluvoxamine Maleate Tablets	Labeling	Level 1	07/05/2002	Withdrawn
Gentamicin Sulfate Ophthalmic Solution USP and Gentamicin Sulfate Ophthalmic Ointment USP	Labeling	Level 1	07/05/2002	Withdrawn
Heparin Sodium Injection USP	Labeling	Level 1	07/05/2002	Withdrawn
Hydrocodone Bitartrate and Acetaminophen Tablets USP	Labeling	Level 1	07/05/2002	Withdrawn
Indomethacin Capsules USP	Labeling	Level 1	07/05/2002	Withdrawn
Itraconazole Capsules	Labeling	Level 1	07/05/2002	Withdrawn
Leucovorin Calcium for Injection	Labeling	Level 1	07/05/2002	Withdrawn
Leucovorin Calcium Tablets USP	Labeling	Level 1	07/05/2002	Withdrawn
Medroxyprogesterone Acetate Tablets USP	Labeling	Level 1	07/05/2002	Withdrawn
Metaproterenol Sulfate Inhalation Solution USP	Labeling	Level 1	07/05/2002	Withdrawn
Metaproterenol Sulfate Syrup USP	Labeling	Level 1	07/05/2002	Withdrawn
Metaproterenol Sulfate Tablets USP	Labeling	Level 1	07/05/2002	Withdrawn
Metoclopramide Tablets USP and Metoclopramide Oral Solution USP	Labeling	Level 1	07/05/2002	Withdrawn
Naproxen Sodium Tablets USP	Labeling	Level 1	07/05/2002	Withdrawn
Naproxen Tablets USP	Labeling	Level 1	07/05/2002	Withdrawn
Paclitaxel Injection	Labeling	Level 1	07/05/2002	Withdrawn
Quinidine Sulfate Tablets, USP	Labeling	Level 1	07/05/2002	Withdrawn
Ranitidine Tablets USP	Labeling	Level 1	07/05/2002	Withdrawn
Risperidone Oral Solution	Labeling	Level 1	07/05/2002	Withdrawn

Risperidone Tablets	Labeling	Level 1	07/05/2002	Withdrawn
Sulfacetamide Sodium Ophthalmic Solution USP and Sulfacetamide Sodium Ophthalmic Ointment USP	Labeling	Level 1	07/05/2002	Withdrawn
Sulfacetamide Sodium and Prednisolone Acetate	Labeling	Level 1	07/05/2002	Withdrawn
Sulfamethoxazole and Trimethoprim Tablets USP and Sulfamethoxazole and Trimethoprim Oral Suspension USP	Labeling	Level 1	07/05/2002	Withdrawn
Theophylline	Labeling	Level 1	07/05/2002	Withdrawn
Theophylline Intravenous Dosage Forms	Labeling	Level 1	07/05/2002	Withdrawn
Tobramycin Sulfate Injection USP	Labeling	Level 1	07/05/2002	Withdrawn
Venlafaxine Hydrochloride Tablets	Labeling	Level 1	07/05/2002	Withdrawn
Verapamil Hydrochloride Tablets	Labeling	Level 1	07/05/2002	Withdrawn
Zolpidem Tartrate Tablets	Labeling	Level 1	07/05/2002	Withdrawn
Bioavailability and Bioequivalence Studies for Orally Administered Drug Products - General Considerations	Biopharmaceutics Draft	Level 1	07/11/2002	Revised
Inhalation Drug Products Packaged in Semipermeable Container Closure Systems	Clinical Medical Draft	Level 1	07/26/2002	New
Potassium Chloride Modified-Release Tablets and Capsules: In Vivo Bioequivalence and In Vitro Dissolution Testing	Generic Drug Draft	Level 1	08/07/2002	Revised
Handling and Retention of Bioavailability and Bioequivalence Testing Samples	Generic Drug Draft	Level 1	08/21/2002	New
Liposome Drug Products: Chemistry, Manufacturing, and Controls; Human Pharmacokinetics and Bioavailability; and Labeling Documentation	Chemistry Draft	Level 1	08/21/2002	New
Clinical Evaluation of Combination Estrogen/ Progestin-Containing Drug Products Used for Hormone Replacement Therapy of Postmenopausal Women	Clinical Medical	Level 1	09/10/2002	Withdrawn
Non-Contraceptive Estrogen Drug Products – Prescribing Information for Healthcare Providers and Patient Labeling	Labeling Draft	Level 1	09/10/2002	Withdrawn
Drugs, Biologics, and Medical Devices Derived from Bioengineered Plants for Use in Humans and Animals	Clinical Medical Draft	Level 1	09/12/2002	New